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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,557	09/11/1998	LINDA MAY PILARSKI	P-1459(O)	2357

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LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER

FONDA, KATHLEEN KAHLER

ART UNIT	PAPER NUMBER
1623	21

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/142,557	PILARSKI, LINDA MAY	
	Examiner Kathleen Kahler Fonda, Ph.D.	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 March 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 171-204 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 171-204 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>19</u> . | 6) <input type="checkbox"/> Other: _____ |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 200 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 200 is indefinite because it fails to recite any steps of a "method of harvesting tissue for organ transplantation." Claim 200 requires that the hyaluronic acid be infused into the patient in need of transplantation, rather than into the donor. Thus the claim is indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless--

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 202 is rejected under 35 U.S.C. 102(e) as being anticipated by FALK et al. (A1). Claim 1 of the reference teaches treatment of organ rejection by administering a composition comprising hyaluronic acid having a molecular weight within the range of claim 202. Thus claim 202 is anticipated.

Claims 171-204 are rejected under 35 U.S.C. 103(a), as set forth in the Office action of 09-13-01 with reference to then-pending claims 103, 106-111, 114-126, 130-136, 138, 139, 141, 143, and 144, as being unpatentable over HAMANN et al. (K) in view of FALK et al. (A).

Applicant claims methods of releasing hematopoietic or dendritic cells, including stem cells or red blood cells, from bone marrow or other tissue by administering hyaluronic acid. Multiple doses and various amounts may be administered.

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Applicant also claims methods of treating allergy or asthma; treating a patient having low levels of red blood cells; harvesting tissue for organ transplantation; mobilizing cells in an *ex vivo* organ; treating organ rejection; and increasing the number of stem cells.

HAMANN teaches that hyaluronic acid stimulates growth of megakaryocyte progenitors; see, for example, the Abstract. HAMANN also specifically refers to implications for treatment of asthma; see the first paragraph following the Abstract. HAMANN specifically states in the last paragraph on page 4078 that the studies described therein "demonstrated that HA causes augmented production of eosinophil [or blood cell] precursor cells specifically through the CD44 receptor."

HAMANN does not explicitly teach administering hyaluronic acid to a patient.

FALK (A) teaches that hyaluronic acid may be administered to patients administered for various therapeutic purposes, in amounts and molecular weight which encompass those of the claims; see column 15, lines 44-49, the claims, and the Examples. FALK (A) also teaches administration of multiple doses at time intervals; see column 10, lines 46-50.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to administer hyaluronic

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acid to a patient in order to stimulate production or release of hematopoietic or dendritic cells, including stem cells or red blood cells. An ordinarily skilled worker would have been motivated to do so, with a reasonable expectation of success, because HAMANN had taught that hyaluronic acid had the activity recited by Applicant, and had suggested its therapeutic potential. FALK (A) had confirmed that hyaluronic acid could be used therapeutically. No criticality or unexpected result is seen to stem from any specific molecular weight or dosage of the claims, or from multiple doses. These specifics of administration would have been obvious in view of the teaching of FALK (A). Because of the teaching of augmentation of blood cell production taught by HAMANN, it would also have been obvious to administer a form of hyaluronic acid for the purpose of treating a patient having low levels of red blood cells; harvesting tissue for organ transplantation; mobilizing cells in an *ex vivo* organ; and increasing the number of stem cells.

Applicant's arguments filed 03-13-02 have been fully considered but they are not persuasive. Applicant argues that HAMANN teaches away from the instant invention because in an assay which, in Applicant's view, would best approximate *in vivo* conditions, HAMANN observed inhibition rather than proliferation

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at certain concentrations. This argument is not convincing because at best, it indicates that achieving proliferation is dosage dependent. Determining a particular appropriate dosage is ordinarily within the level of skill of a person having ordinary skill in the art, and there is no reason to expect that it would not be in this instance. Applicant further argues that neither HAMANN nor FALK teaches release or mobilization of cells. It is not relevant to the inquiry at hand that HAMANN and FALK may not have recognized this particular benefit of administration of hyaluronic acid, because HAMANN suggests and FALK teaches *in vivo* administration. See *Mehl/Biophile Int'l Corp. v. Milgraum*, 52 USPQ2d 1303 (Fed. Cir. 1999).

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

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INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.


Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
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